Sections Included in this Document and Document History

1. Purpose

The procedure establishes the process to track and investigate potential non-conformances in the [Laboratory Name] Quality Management System. The cornerstone of preventive action is written and retrievable documentation of actions taken and follow-up monitoring to determine that preventive actions have been implemented and documented.

2. Scope

This procedure is applicable to all organizational units in the [Laboratory Name].

3. Responsibilities

A. [Third Level Manager]:

- initiates, performs, and oversees preventative action.

B. [Second Level Manager]:

- implements and oversees preventative action.

C. [First Level Manager]:

- ensures preventive action procedure is implemented and monitored, and
- identifies preventive actions in management review.

D. [Quality Management System Manager]:

- verifies implementation of management review action plans, and

- maintains preventive action plans and documentation.

E. [Staff]:

- initiates and performs identified preventive action.

4. Background

None

5. References

None

6. Procedure

A. Preventive Action

1. Preventive action plans are part of a proactive process for improvement rather that a reaction to problems or complaints. Preventive action includes the use of sources of information such as processes and work operations which affect quality, audit results, quality records and complaints to detect, analyze and eliminate potential causes of non-conformances.

2. Preventive action includes the use of measurable quality objectives and requirements, validation and review processes, audits and management review, feedback and complaints, and the quality system and the International Organization for Standardization and the International Electrotechnical Commission (ISO/IEC) requirements.

3. Proficiency samples, internal quality control samples and quality control (QC) charts are monitored for trends or biases.

4. The laboratory performs function verification and preventive maintenance on instrumentation. Service contracts with periodic manufacturer maintenance may be in effect for identified instruments.

5. Documented investigation using the corrective action form is initiated if a potential nonconformity is identified from any of the above processes.

6. Examples requiring preventive action measures are:

- accumulation of minor product non-conformities of a similar character,
- recurring problem with a process or a work operation,
- identified trends or biases from internal quality control schemes,
- instrument performance problems reported by servicing representatives,
- complaints, and
- preventive action plans resulting from audit or management review.

7. Preventive actions are closed when the results of the investigation are approved.

7. Definitions	Non-conformance – This is a non-fulfillment of a specified, or implied, requirement of the Quality Management System or of a quality work product. Fitness-for-use criteria and evaluations determine the significance of a nonconformance. Preventive action – This is an endeavor taken to eliminate the cause of a potential nonconformity or other potentially undesirable situation to prevent occurrence.
8. Records	Corrective Action form Action plans
9. Supporting Documents	[Laboratory Name]-Management Review
10. Attachments	None

Document History					
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